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Section 510 (K) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

The submitter of this pre-market notification is:
Carlos O. Acosta
Philips Lifeline
111 Lawrence Street,
Framingham, MA 01702-8156
Tel: 508-988-1366
Fax: 508-988-1015
Email: carlos.acosta1@philips.com

DEC 1 2010

Alternate contact:
David R. Jones
Philips Home Monitoring
111 Lawrence Street,
Framingham, MA 01702-8156
Tel: 508-988-1658
Fax: 508-988-1015
Email: david.r.jones@philips.com

Date of summary: Thursday, October 28, 2010

Device name: The M3810A Philips Telemonitoring System with eDevice BridgeD130

Common name: Physiological Transmitter and Receiver.

Classification names are as follows:

Classification Name	Regulation Number	ProCode
Physiological Signal Transmitters and Receivers	870.2910	DRG
Non-invasive Blood Pressure	870.1130	DXN
Electrograph	870.2340	DPS
Patient scale	870.2720	FRW
Oximeter	870.2700	DQA
Glucose Test System	862.1345	CGA

Predicate Devices: The modified device is substantially equivalent to the previously cleared Modification of Physiological Signal Transmitter & Receiver pursuant to K993169 (September 22, 1999).

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Modifications	The addition of the eDevice BridgeD130 wireless communication option to transmit data to the backend clinical server. This device is substantially equivalent to the previous cleared Honeywell HomMedtGenesis DM Remote Patient Care Monitor K101242, the difference between the two devices is that the eDevice BridgeD130 is an external communication device and the Honeywell HomMedtGenesis DM Remote Patient Care Monitor is an internal communication module.
Intended Use	The subject device has the same intended use and indications for use as the legally marketed predicate devices with the addition of wireless communication option: The M3810A Philips TeleMonitoring System with eDevice BridgeD130 is intended to be used upon prescription of a licensed physician or authorized healthcare provider by patients as a means to automatically collect and transmit medical information, such as weight, blood pressure, and non-diagnostic ECG, over normal residential telephone lines or cellular connectivity, between a patient, typically at home, and a health care professional at the authorized provider. The device does not send any real-time alarms. Clinical judgment and experience are required to check and interpret the information delivered.
Technological characteristics	The modify device has the same fundamental technological characteristics as the legally marketed predicate device.
Performance data	Verification, validation, and testing activities were conducted to establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. Testing involved system level tests, functionality/performance tests, software and safety testing from hazard/risk analysis. Completed electrical safety testing, EMC testing, mechanical durability, safety (operator and patient), temperature/humidity and radio telemetry testing and user evaluations for consumer accuracy demonstrated compliance with applicable standards. Acceptance criteria were based on the specification cleared for the predicate device, the specifications of the subject device and test results showed substantial equivalence. The results demonstrate that the M3810A Philips Telemonitoring System with the addition of a cellular connectivity device meets all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 1 2010

Lifeline Systems, Inc.
Philips Medical Systems North America, Co.
c/o Mr. Carlos O. Acosta
Sr. Quality Assurance & Regulatory Manager
111 Lawrence Street,
Framingham, MA 01702-8156

Re: K103214
Trade/Device Name: M3810A Philips Telemonitoring System with eDevice BridgeD130
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DRG
Dated: October 28, 2010
Received: November 1, 2010

Dear Mr. Acosta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

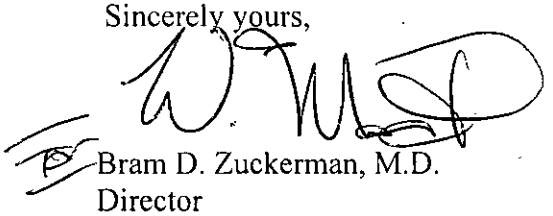
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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3.2 Indications for Use

DEC 1 2010

510 (k) Number (if known): K103214

Device Name: M3810A Philips Telemonitoring System with eDevice BridgeD130

The M3810A Philips TeleMonitoring System with eDevice BridgeD130 is indicated for patients at home, who are capable and willing to self administrate this device, upon the prescription of their healthcare provider, to collect and transmit medical information such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone lines or cellular connectivity to the healthcare provider. The device may be used for the management of congestive heart failure, hypertension, ischemic heart disease, weight management, cardiovascular risk management, post cardiovascular surgery, post myocardial infarction, and other post cardiac events. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103214